

SECTION: CLAIM AMENDMENTS

Pursuant to 37 CFR 1.121, a complete listing of all claims in the application, and their status, is set forth below. The text of each pending claim is also provided. Please amend the pending claims as follows, wherein added matter is underlined and deleted matter is ~~stricken through~~ or ~~[[double bracketed]]~~ in the text of the currently amended claims, relative to the immediate prior version. The claims in this listing are deemed to replace all prior claims in the application.

1-115 (Cancelled)

116. (Original) An apparatus for determining a cardiac shock strength, comprising:

- (a) a sensor for sensing the electrical activity of the heart, including the change in the T-wave with respect to time of a cardiac signal and including fibrillation; and
- (b) a controller, connected to the sensor, which provides a test shock of a test-shock strength and at a test-shock time relating to the change in the T-wave with respect to time, and to determine the cardiac shock strength as a function of the test-shock strength.

117. (Original) An apparatus for determining and delivering a therapeutic cardiac shock, comprising:

- (a) a plurality of electrodes, at least one electrode being adapted for sensing cardiac signals and at least one electrode being adapted for delivering shocks to the heart;

- (b) a shock subsystem connected to the at least one electrode for delivering shocks and which is capable of generating test shocks and therapeutic cardiac shocks; and
- (c) a ULV subsystem connected to the shock subsystem and for providing test-shock information to the shock subsystem, the test-shock information including test-shock strength and test-shock time relating to a change in one or more cardiac signals with respect to time, and for determining the shock strength of the therapeutic cardiac shocks as a function of the test-shock strength.

118. (Original) An implantable cardioverter defibrillator system for determining and delivering an optimal programmed first-shock strength based on the upper limit of vulnerability, comprising:

- (a) a plurality of implantable electrodes;
- (b) a shock delivery subsystem, connected to the electrodes; and
- (c) a ULV subsystem comprising;
 - i) a sensor, connected to the electrodes, for sensing the electrical activity of the heart, including a change with respect to time of the T-wave of a cardiac signal and including the presence of fibrillation;
 - ii) a timer connected to the sensor for providing a series of shock times, timed relative to the maximum derivative of the T-wave;
 - iii) a test-shock driver, connected to the timer, for transmitting timing and amplitude information regarding T-wave test shocks;

- iv) a memory unit, connected to the test shock driver and the shock subsystem, for storing programmable values such as pacing cycle length, timing intervals, an initial shock strength, and values for incrementing and decrementing shock strength; and
 - v) a controller, connected to the sensor, test-shock driver, and shock subsystem for incrementally varying shock strength and the shock times; whereby the system provides a test shock having a shock strength and shock time selected by the controller;
- (d) whereby:
- (i) the shock subsystem delivers an initial test shock to the heart at an initial shock strength and an initial shock time; and if the heart does not fibrillate
 - (ii) the system delivers a sequence of test shocks to the heart at the same shock strength and different shock times; and if the heart does not fibrillate
 - (iii) the system decreases the shock strength, a strength decrement and delivers test shocks at a sequence of intervals; and if the heart does not fibrillate
 - (iv) the system repeats steps (d) (i) – (iii) until the heart fibrillates, whereby the shock strength of the test shock immediately prior to the test shock that induces fibrillation represents the upper limit of vulnerability, and whereby the optimal programmed first shock strength of an implantable cardioverter defibrillator system is predicted by a fixed increment in relation to the energy level determined to be the upper limit of vulnerability.

119. (Original) The system of claim 118, wherein the system operates when the heart is in its native rhythm.

120. (Original) The system of claim 118, wherein the system operates when the heart is paced, the system further comprising a pacer for overdrive pacing the heart, the timer being electrically connected to the pacer and shock times further being timed in relation to one or more pacing spikes from the pacer according to a time delay.

121. (Original) The system of claim 118, wherein the programmed shock strength of an implantable cardioverter defibrillator is a value incrementally higher than the upper limit of vulnerability.

122. (Original) The system of claim 118, wherein the strength decrement is at least 2 Joules.

123. (Original) The system of claim 118, wherein the timer provides at least four time delays comprising time delays measured from a base time, measured from a predetermined point on an electrogram to a the maximum of the first derivative of the T-wave with respect to time, plus an offset interval ΔT .

124. (Original) The system of claim 123, wherein the offset intervals are: 0 milliseconds before the maximum derivative of the T-wave, 20 milliseconds before the maximum derivative of the T-wave, 40 milliseconds before the maximum derivative of the T-wave, and 20 milliseconds after the maximum derivative of the T-wave .

125. (Original) The system of claim 123, wherein the offset intervals are: 0 milliseconds before the maximum derivative of the T-wave, 20 milliseconds before the maximum derivative of the

T-wave, 20 milliseconds after the maximum derivative of the T-wave, and 40 milliseconds after the maximum derivative of the T-wave .

126. (Original) The system of claim 118, wherein the electrode arrangement consists of implanted electrodes.

127. (Original) The system of claim 126, wherein the implanted electrodes includes at least one intracardiac electrode.

128. (Original) The system of claim 126, wherein the implanted electrodes includes at least one intravascular electrode.

129. (Original) The system of claim 126, wherein the implanted electrodes includes at least one subcutaneous electrode.

130. (Original) The system of claim 126, wherein the implanted electrodes includes at least one submuscular electrode.

131. (Original) The system of claim 126, wherein the implanted electrodes includes at least one epicardial electrode.

132. (Original) The system of claim 126, wherein the electrodes include at least one cutaneous electrode.

133. (Original) The system of claim 118, wherein a sequence of one or more test shocks are delivered at only one shock strength, and if fibrillation is not detected, the programmed shock strength is set to a value that is a fixed increment greater than the test shock strength.

134. (Original) The system of claim 133, in which the energy level is 15 Joules.

135. (Original) The system of claim 133, wherein the fixed increment is 5 J above the energy level.

136. (New) A method for determining a cardiac shock strength, comprising the steps of:

- (a) sensing a change with respect to time in a T-wave of an electrical cardiac signal, wherein said change with respect to time is an extreme absolute value calculated by a method selected from the group consisting of a finite difference, an ordinary derivative, a directional derivative, a gradient and a partial derivative, an implicit differential, a variance calculation, a bounded variation calculation, a radial displacement vector, and a tangent vector approximation. the extreme absolute value being selected from the group consisting of a minimum absolute value, a minimum value and a maximum value;
- (b) delivering a test shock by:
 - (i) delivering a test shock at a test-shock strength and at a test-shock time relating to sensing the change with respect to time in the T-wave; and
 - (ii) sensing for cardiac fibrillation; and

- (c) if fibrillation is not sensed, repeating step (b) at the test-shock strength and at a different test-shock time relating to the change in the T-wave; and
- (d) if fibrillation is sensed, setting the cardiac shock strength as a function of the test-shock strength.